

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

**This Document Relates to All Actions**

MDL No. 2875

Honorable Renée Marie Bumb,  
Chief District Court Judge

**DEFENDANT ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.’S**  
**REPLY IN SUPPORT OF OBJECTIONS TO AND MOTION TO REVERSE**  
**SPECIAL MASTER ORDER 98 GRANTING PLAINTIFFS’ MOTION FOR**  
**RULE 37 SANCTIONS**

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Plaintiffs devote the bulk of their opposition brief to lodging ad hominem attacks on ZHP, suggesting that ZHP should be accountable for actions of the Chinese government, insinuating that it could somehow have influenced the government, and speculating that because ZHP only produced a purportedly “small” number of documents from Maggie Kong’s files, others must “exist.” (Opp’n at 1, 31-32.) These arguments cannot sustain an award of sanctions, which must be based on real evidence of sanctionable conduct, not mere innuendo and speculation.

The Special Master’s order is all the more improper because of the draconian nature of the sanctions: (1) an adverse inference that would effectively undo Plaintiffs’ burden of proof in all valsartan trials; and (2) monetary penalties that require a finding of criminal contempt. Plaintiffs argue that the Special Master’s approach was “measured” because he did not strike ZHP’s answers or deem all of their allegations admitted. (Opp’n at 32.) But instructing the jury that ZHP’s CEO was involved in a purported “cover up” is effectively tantamount to directing a verdict against the company. And Plaintiffs’ argument that ZHP somehow “advocated for” an \$877,000 penalty is simply not true.

## **ARGUMENT**

### **I. ZHP DID NOT ENGAGE IN SANCTIONABLE CONDUCT.**

#### **A. ZHP Acted In Good Faith And With Reasonable Diligence To Secure Mr. Chen’s Presence For His Deposition.**

Unsurprisingly, Plaintiffs do not cite any cases holding that a defendant can

be sanctioned for the decisions of a foreign government. Nor do Plaintiffs even acknowledge most of the cases cited by ZHP **precluding** such sanctions. Plaintiffs do attempt to distinguish *Westinghouse* on the ground that the defendant there made “concerted efforts” to “get the Canadian government . . . to allow the production” of documents at issue, whereas ZHP’s efforts were, in their view, “inadequate.” (Opp’n at 24-25 (citing *In re Westinghouse Elec. Corp. Uranium Conts. Litig.*, 563 F.2d 992, 997 (10th Cir. 1977).) But the party **seeking** discovery in that case actually “sought the aid of the Canadian courts.” *Westinghouse*, 563 F.2d at 995. Here, by contrast, Plaintiffs concede that they “did not resort” to any such efforts—namely, pursuing the procedures under the Hague Convention.<sup>1</sup> In any event, Plaintiffs have no legitimate basis for attacking ZHP’s efforts to comply with its discovery obligations.

**First**, Plaintiffs contend that ZHP “delay[ed]” in seeking permission from the Chinese government for Mr. Chen to travel for a deposition by waiting until early June 2021, “after the deposition was originally scheduled to take place.” (Opp’n at 25.) But in *Westinghouse*, the request was made **after** entry of the discovery order. 563 F.2d at 998. Here, by contrast, ZHP initiated the government approval process weeks **before** Judge Kugler affirmed the Special Master’s decision ordering Mr.

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<sup>1</sup> While Plaintiffs note that “a party is not required to resort to the Hague Convention protocols” (Opp’n at 29), that is a different question from whether Plaintiffs’ failure to pursue such procedures bears on the propriety of sanctions.

Chen's deposition. Moreover, Plaintiffs ignore that on May 3, 2021, the Special Master postponed Mr. Chen's deposition until June 21-23, 2021, so that ZHP's motion for a protective order under the "apex" witness doctrine could be supplemented with the deposition testimony of former ZHP Vice Chairman Jun Du. (See ECF [1220](#) 45:10-18.) Given the postponement of Mr. Chen's deposition on May 3, 2021, ZHP did not file the application for Mr. Chen's travel permit until closer to the rescheduled date of his deposition of June 21-23, 2021. These circumstances foreclose Plaintiffs' complaints regarding the timing of ZHP's efforts.

**Second**, Plaintiffs also argue that the declaration signed by the ZHP employee who completed the application, Sihan Lu, "illustrates the inadequacy of ZHP's efforts." (Opp'n at 25.) But, as explained in ZHP's opening brief, neither Plaintiffs nor the Special Master cited anything suggesting that the application was inadequate. By contrast, ZHP submitted a declaration from an expert on Chinese law explaining why the application was "fully consistent with long-standing and well-established Chinese practice." (deLisle Decl. ¶ 18 (ECF [2175-2](#))). While Plaintiffs respond that the declaration was "late" and therefore "correctly precluded, as a similar filing by Professor deLisle was rejected by another court" (Opp'n at 27-28 (citing *Stross v. NetEase, Inc.*, No. CV 20-00861-AB (PJWx) et al., 2020 WL 5802419, at \*1 (C.D. Cal. Aug. 20, 2020))), *Stross* is inapposite. There, the defendant sought to submit a declaration in support of *its* motion to dismiss on *forum non conveniens* grounds four

months after it had filed the motion. 2020 WL 5802419, at \*1 n.2. Here, by contrast, the Special Master effectively invited the declaration on September 8, 2022, when he stated that there “[s]hould . . . be a declaration” addressing ZHP’s position (ECF [2182](#) 41:24-42:6), and ZHP promptly submitted the declaration the following month. (*See generally* deLisle Decl.)<sup>2</sup>

In any event, Plaintiffs’ procedural objection to the declaration is beside the point because “[t]he moving party bears the burden of establishing that sanctions are warranted under Rule 37.” *Griffin v. Work*, No. 1:19-cv-00882-JPH-MPB, 2020 U.S. Dist. LEXIS 252397, at \*2 (S.D. Ind. June 2, 2020). As explained below, Plaintiffs’ arguments that ZHP’s efforts were inadequate do not come close to carrying that burden.

*Plaintiffs’ assertion that “ZHP tasked an inexperienced and uninformed administrator” with completing Mr. Chen’s permit application.* (Opp’n at 26.) This is speculation. Ms. Lu is the coordinator for general government matters, and nothing in her declaration suggests that she was unfamiliar with any aspect of the process for submitting an application for a permit to travel out of China. To the

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<sup>2</sup> Plaintiffs also claim in a footnote that the declaration “is nothing more than an ipse dixit conclusory opinion,” not entitled to any substantive weight. (Opp’n at 28 n.13.) But the declaration is supported by multiple citations to sources (e.g., “party and state documents”) substantiating Professor deLisle’s opinions. (*See* deLisle Decl. ¶ 16 n.1.)

contrary, the declaration details the steps Ms. Lu took to apply for Mr. Chen's travel permit, provides the information she received from the different approval authorities as she was doing so, and shows that she fully and competently completed the application process. (See Lu Decl. ¶¶ 4-15 (ECF [1900-1](#)).)

*Plaintiffs' contention that the application is "materially incomplete" because it does not provide the "Country/Region"; does not adequately specify the "[r]easons for application"; and does not include the "[o]pinions from the leader in charge."* (Opp'n at 26.) Plaintiffs are neither experts in completing the travel application form nor knowledgeable with respect to the procedures involved in submitting travel permit applications. Moreover, Plaintiffs fail to understand what is meant by "Opinions from the leader in charge," much less what opinions were supposedly necessary. As the President of ZHP, Mr. Chen *is* the "leader in charge"; thus, there is no person at ZHP who oversees him and could have provided an opinion regarding the application. That is why those parts of the application were left blank. And while Plaintiffs assert that the application should have mentioned that Mr. Chen "was ordered by a federal court in the United States to appear for a deposition" (Opp'n at 26 (citation omitted)), Ms. Lu clearly stated in her declaration that the approval authority understood that Mr. Chen was seeking to travel out of



China for a deposition (*see* Lu Decl. ¶ 3).<sup>3</sup> Accordingly, the reasons for the application were conveyed to—and understood by—the PRC government.

*Mr. Chen obtained permission to leave China to meet with valsartan customers in 2019.* According to Plaintiffs, the fact that the PRC allowed Mr. Chen to leave China in 2019 for business but rejected his application to do so for purposes of a deposition “is clear evidence that the blocking statute is applied in a biased manner to frustrate the United States Courts.” (Opp’n at 28.) But even assuming Plaintiffs were correct that China applies its laws in a biased manner, ZHP cannot be punished for the actions of a foreign government. Rather, Plaintiffs’ argument merely highlights that ZHP could not comply with Judge Kugler’s order “because of foreign law.” *Westinghouse*, 563 F.2d at 997 (quoting *Societe Internationale Pour Participations Industrielles et Commerciales, S.A. v. pll*, 357 U.S. 197, 212 (1958)).<sup>4</sup>

In short, the record is clear that ZHP’s attempt to comply with the Court’s

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<sup>3</sup> There is no truth to Plaintiffs’ suggestion that the Special Master ordered ZHP to attach a copy of his ruling to Mr. Chen’s application. (*See* Opp’n at 27 (citing ECF [1696](#) 6:17-20).) What the Special Master told ZHP’s counsel was that “[y]ou can report to your counterparts in China that the Court has ordered that the deposition be taken by December 15th so that they understand that there is a deadline in place and hopefully this deadline can be accommodated.” (ECF [1696](#) 6:17-20.)

<sup>4</sup> As Professor deLisle explains, a request by a high-ranking official to leave the country as part of a foreign judicial proceeding would receive greater “scrutiny” than one for a purely business purpose. (*See* deLisle Decl. ¶ 25.)

order regarding Mr. Chen “was made in the best of faith,” that the Chinese government “considered” but ultimately “denied” Mr. Chen’s application, and that the Special Master “abused [his] discretion” in imposing sanctions on ZHP for any purported non-compliance with SMO 28. *Westinghouse*, 563 F.2d at 996, 998.

**B. ZHP Produced The Documents That The Special Master Found Remain Outstanding.**

Plaintiffs appear to concede that ZHP has produced all non-privileged documents in its possession that fall into two of the four categories addressed by SMO 54: (1) all documents referencing “TC-201729,” the project name for a lab-scale study of irbesartan; and (2) all documents relating to the batch testing for nitrosamines referenced in PRINSTON0075797. They nonetheless contend that “ZHP has not fully complied with SMO 54” with respect to the custodial file of Mr. Chen’s chief of staff, Ms. Kong, and an investigative report regarding an impurity in irbesartan. (Opp’n at 29.) In so arguing, Plaintiffs essentially urge the Court to disregard ZHP’s counsel’s sworn certification attesting that ZHP had produced all non-privileged documents within its possession and credit Plaintiffs’ rank speculation that “more documents exist.” (*Id.* at 30-32.) The Court should reject Plaintiffs’ invitation to do so.

*First*, Plaintiffs argue that counsel’s “certification was never part of the record before the Special Master because ZHP never submitted it.” (*Id.* at 30.) This argument ignores the Special Master’s statement that the “record should reflect”

such a “certification” (ECF [2182](#) 39:3-8), which counsel provided to Plaintiffs on October 21, 2022 (Objs. Ex. 1 (“Bernardo Cert.”)).

**Second**, Plaintiffs also claim that the certification “simply repeats ZHP’s” “false claims from the September 8, 2022 oral argument that it had produced everything required pursuant to SMO 54.” (Opp’n at 30 (citing ECF [2182](#) 37:10-39:2).) According to Plaintiffs, the statements on the record were “false” because ZHP produced additional documents three days before counsel signed the certification. (*Id.*) But what counsel **actually** told the Special Master was that “the document issues **were being addressed** and have been addressed.” (ECF [2182](#) 37:10-13 (emphasis added).) The fact that ZHP produced a few more documents is entirely consistent with counsel’s representation and underscores ZHP’s good faith.

**Third**, Plaintiffs also insist that ZHP has still failed to comply with SMO 54 because only a “small” number of documents were produced from Ms. Kong’s and Mr. Chen’s custodial files, and none were created in the three weeks after Novartis discovered trace amounts of NDMA in ZHP’s valsartan. (Opp’n at 31-32.) In truth, ZHP has produced a significant number of documents from Ms. Kong’s file, **spanning more than 1,000 rows of Bates numbers**. (*See* Ex. 1 to Bernardo Cert.) Moreover, in SMO 54, the Special Master credited ZHP’s representation that a “relatively low document count is to be expected” because ZHP had already produced a far greater number of documents from numerous custodians with far

more active involvement in valsartan-related matters. (See ECF [1753](#), at 4 (noting that ZHP “states that the relatively low document count” for Mr. Chen’s files “is to be expected in that this production is occurring well after production by the 80 initially-identified document custodians and the peripheral role played by most of the newly added document custodians”).) Plaintiffs’ insistence that “more documents exist” has no basis other than their speculation and say-so and cannot withstand the sworn certification from ZHP’s counsel that there are *no* additional responsive documents within ZHP’s possession. (See Bernardo Cert.) See, e.g., *Cache La Poudre Feeds, LLC v. Land O’Lakes, Inc.*, 244 F.R.D. 614, 631 (D. Colo. 2007) (denying plaintiff’s motion for sanctions for failing to produce certain documents; “[o]n the available record, the court must accept, at face value, [d]efendants’ representations that they did not keep” such documents); *Prokosch v. Catalina Lighting, Inc.*, 193 F.R.D. 633, 637 (D. Minn. 2000) (denying motion for sanctions based on purported failure to produce documents because a court “must accept, at face value, a party’s representation that it has fully produced all materials that are discoverable” regardless of whether explanation is implausible) (citation omitted).

At bottom, Plaintiffs appear to be suggesting to the Court that because ZHP is a Chinese company, the Court should not believe counsel’s representations regarding the company’s careful and repeated reviews of its files and should instead

assume that it acted improperly.

*Fourth*, Plaintiffs’ claim that ZHP is not in compliance with SMO 54 because it has not “produce[d] all drafts and metadata for the irbesartan investigation report” fails for the same reason. (Opp’n at 31.) ZHP’s counsel certified that he had “personally investigated the steps taken to determine whether [that document] currently exists in native format” and “learned that [it] was located during ZHP’s collection of documents only in hard copy, and was scanned to PDF for production.” (Bernardo Cert. ¶ 9.) Plaintiffs have no evidence that counsel’s certification is false; hence, the Court “must accept [ZHP’s] representation[] that” no native electronic versions of the investigative report exist. *Prokosch*, 193 F.R.D. at 637.

In sum, Plaintiffs have failed to establish that either of the two bases underlying the Special Master’s ruling supports the imposition of sanctions.

## **II. THE SEVERE SANCTIONS ORDERED BY THE SPECIAL MASTER ARE DISPROPORTIONATE AND UNCONNECTED TO THE ALLEGED VIOLATIONS.**

Even if any sanctions were appropriate (and none are), Plaintiffs cannot defend either of the sanctions imposed: a draconian “adverse inference” that would relieve Plaintiffs of the need to prove their case and a substantial criminal fine.

### **A. The Special Master’s “Adverse Inference” Sanction Is Excessive And Unjust.**

Plaintiffs’ argument that the adverse inference ordered by the Special Master is “measured” because he did not strike ZHP’s answers or deem Plaintiffs’

allegations admitted misses the point. (Opp’n at 32.) As explained in ZHP’s opening brief, the Special Master’s sanction would “require[]” the jury to accept disputed facts at the core of this case: i.e., that “ZHP knew of the contamination at least by July of 2017” and “covered [it] up” at “Baohua Chen’s direction.” (Objs. at 30-31 (citations omitted).) This sanction, for all practical purposes, would “have much the same effect as a default judgment” or directed verdict, *Gertcher v. Therrian*, No. 2:20-cv-240, 2022 WL 842655, at \*6 (W.D. Mich. Mar. 22, 2022), and therefore can only be justified by the same considerations—i.e., “the six *Poulis* factors” (Opp’n at 32); *see, e.g., FS2 Cap. Partners, LLC v. Church*, No. 14-4933, 2015 WL 246339, at \*5 (E.D. Pa. Jan. 16, 2015). Apart from asserting in a conclusory manner that the Special Master correctly applied those factors (Opp’n at 32), Plaintiffs do not explain why the factors are satisfied. They are not.

The Special Master’s “adverse inference” is also unwarranted because it is untethered to any supposedly missing discovery. To the extent Plaintiffs try to defend the “adverse inference,” they do so by claiming that Mr. Chen “was a key player” in valsartan manufacturing and sales, and that certain documents “would have . . . been very informative” if produced. (Opp’n at 34-35.) But Plaintiffs concede that an adverse inference instruction requires a “showing” that “‘a reasonable jury could infer that the [missing discovery] contained’ the information the jury is instructed to infer.” (*Id.* at 35-36 (quoting Objs. at 32 & *Emerson v.*

*Wetherill*, No. CIV. 92-4082, 1994 WL 249769, at \*3 (E.D. Pa. June 1, 1994)).)

With respect to Mr. Chen, that means demonstrating that the CEO would have testified to directing a “cover-up” of nitrosamine impurities in July 2017. Plaintiffs cannot make such a showing. Plaintiffs primarily rely on the fact that the July 2017 email was sent to two people who “reported directly” to Mr. Chen (Opp’n at 34), but Plaintiffs offer nothing to support their speculation that the email’s recipients would have passed it along to their superior, Mr. Chen. And the only evidence that does exist—deposition testimony from those recipients—is directly to the contrary. (*See* Objs. at 12-13.) Plaintiffs dismiss this evidence as “weak denials and deflections” (Opp’n at 34), but they have no evidence to the contrary. In any event, Plaintiffs cannot show any real prejudice. Plaintiffs have the July 2017 email itself, they have deposed its recipients, and they are free to argue their interpretation of the email and testimony to the jury.<sup>5</sup> They also rejected ZHP’s proposal for Mr. Chen to answer questions in writing. (*See* ECF No. [1900](#), at 21 n.9.) As Judge Kugler already ruled,

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<sup>5</sup> Plaintiffs’ brief includes an extended recitation of Mr. Chen’s high-level, supervisory role in “the development, manufacture, sale, and recall of . . . valsartan.” (Opp’n at 9; *see id.* 9-17.) For example, they point to a document that names him “general manager” of the “quality unit” and to a statement in which he took “full responsibility for the company’s operations.” (*Id.* at 10-11 (citation omitted).) But these are merely acknowledgements of his role at the top of the corporate structure. So too is Plaintiffs’ assertion that Mr. Chen set broad corporate goals to reduce costs and increase market share. (*See id.* at 12.) Such evidence does not in any way support the claim that Mr. Chen orchestrated a purported “cover-up.”

the email’s meaning presents a factual question for the jury, which is why the Court denied Plaintiffs’ motion for partial summary judgment on their fraud-based claims. (*See* Objs. at 12.)<sup>6</sup> Plaintiffs understandably prefer not to have to prove their case at trial, but that is no basis for sanctioning ZHP.

Plaintiffs’ claim of inadequate document production likewise fails to support an “adverse inference,” because, as previously discussed, ZHP fully complied with its document production obligations by 2022. While Plaintiffs complain that ZHP should have produced native versions of the 2017 email and an investigation report (both of which focused on *irbesartan*, not valsartan), they do not explain how they have been prejudiced by the lack of metadata, much less how those data would have supported the Special Master’s adverse inference. (*See* Opp’n at 22-23, 35.) Plaintiffs also contend that fewer documents have been produced for Mr. Chen and Ms. Kong than they expected, particularly from May-June 2018, and suggest there must be more. (*Id.* at 17-18, 35.) Even assuming there were any truth to that claim—which there is not—Plaintiffs cannot relate these imagined documents to the sanction imposed by the Special Master. And while Plaintiffs contend that this was a “crucial period of time” (*id.* at 35), that is not enough. The relevant inquiry is

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<sup>6</sup> Plaintiffs argue that defendants’ interpretation of the email is based on “inadmissible” “hearsay” testimony by Jucai Ge. (Opp’n at 34-35.) But the Rules of Evidence do not apply to a sanctions motion, and Ms. Ge testified to her own understanding of the email, not to the understanding of an absent declarant.



whether the purportedly “missing” documents would contain evidence of a company-wide cover up that purportedly began a year earlier. There is no basis to conclude that they would.

In short, the “adverse inference” ordered by the Special Master would be completely disproportionate and improper even if ZHP had committed any sanctionable conduct.

**B. Plaintiffs Are Not Entitled To Monetary Sanctions Beyond Their Fees And Costs In Seeking Discovery.**

Plaintiffs also fail to justify the imposition of an enormous criminal fine on ZHP. The Special Master ordered Plaintiffs to propose a “substantial monetary penalty” that “[they] believe[] is appropriate under the circumstances.” (SMO No. 98 at 38, 40.) In response, Plaintiffs asserted that ZHP should pay a daily fine of \$1,000.00 per day beginning on December 15, 2021, which would amount to more than \$877,000. (ECF No. [2731-1](#), at 15-16.) Plaintiffs argue that “ZHP advocated for” a monetary sanction by citing to *In re Sealed Case*, 932 F.3d 915 (D.C. Cir. 2019), which “affirm[ed] civil contempt sanctions, including a daily fine of \$50,000.” (Opp’n at 37 (citation omitted).) That is false; ZHP’s position was *exactly the opposite*. ZHP cited *In re Sealed Case*, which imposed a daily fine, not as a model, but rather as an example of sanctions that are not available here. As ZHP explained, because Plaintiffs here did not request monetary sanctions, they “forfeited any right” to them. (ECF [1900](#), at 34.)

Plaintiffs barely bother to defend the fine on the merits, offering just a three-sentence argument that it “would be permissible ‘to coerce ZHP to comply with any outstanding discovery.’” (Opp’n at 38 (citation omitted).) But there is no outstanding discovery; as explained above, Plaintiffs’ contention that ZHP has produced “inadequate documents” (*id.*) is wrong. And in any event, for a contempt fine to be justified as coercive, “the contemnor [must be] afforded an opportunity to purge . . . through compliance” with the court order. *Int’l Union, United Mine Workers of Am. v. Bagwell*, 512 U.S. 821, 829 (1994). The Special Master did not suggest that the fine could be purged through compliance, or even that compliance would stop the continued growth of the fine (which accrues until it is paid). Rather, it is a criminal penalty, and like any other criminal penalty, demands a host of procedures that the Special Master never employed. Even the Special Master recognized as much, noting at a recent discovery conference that “maybe [he] went a little bit too far” in suggesting that he could impose a substantial “monetary sanction of X dollars per day for every day” of ZHP’s alleged noncompliance with discovery. (ECF No. [2763](#) 31:5-17.) For this reason, too, the Special Master’s Order should be reversed.

### **CONCLUSION**

For the foregoing reasons, as well as those set forth in ZHP’s opening brief, the Court should reverse SMO 98.

Dated: July 8, 2024

Respectfully submitted,

By: /s/ Jessica Davidson

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that on July 8, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ Jessica Davidson

Jessica Davidson (NY Bar No. 6034748)